

The Claims:

1. A membrane system comprising:  
an internal compartment defined by said membrane system;  
an interior wall surrounding the internal compartment, wherein fluid permeability of said interior wall is responsive to osmolarity of an osmotic core comprised in said internal compartment; and  
a fluid-permeable exterior wall surrounding the interior wall.
2. The membrane system of claim 1 wherein the interior wall and the exterior wall are in contacting relationship.
3. The membrane system of claim 1 wherein the fluid permeability of said interior wall increases in response to a decrease in the osmolarity of the osmotic core.
4. The membrane system of claim 1, wherein said interior wall comprises a hydrophobic substance and a hydrophilic substance, and said exterior wall is semipermeable.
5. The membrane system of claim 4 wherein the hydrophilicity of the hydrophilic substance is osmosensitive.
6. The membrane system of claim 4, wherein said hydrophilic substance exhibits an aqueous solubility responsive to osmotic pressure and/or ionic strength of said osmotic core.
7. The membrane system of claim 6, wherein the hydrophilic substance provides increased permeability of the interior wall in response to a decrease in the osmotic pressure and/or the ionic strength of said osmotic core.

1           8.     The membrane system of claim 4, wherein said interior wall comprises a  
2 polymer composition and said hydrophilic substance exhibits an aqueous solubility  
3 responsive to degree of hydration of said polymer composition.

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5           9.     The membrane system of claim 4, wherein said inner wall comprises a  
6 member selected from the group consisting of hydrogel polymers, osmopolymers,  
7 osmotically-effective compounds, suspending agents, compounds for forming passageway,  
8 pore formers polypeptides, proteins, polysaccharides, cellulose derivatives, surfactants,  
9 synthetic polymers and inorganic polymers.

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11           10.    The membrane system of claim 9, wherein said hydrophobic substance  
12 comprises ethyl acetate or cellulose acetate; said hydrophobic membrane comprises  
13 hydroxyalkylcellulose; and said semipermeable substance comprises cellulose acetate.

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15           11.    The membrane system of claim 1, wherein said internal compartment  
16 comprises a therapeutic agent.

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18           12.    The membrane system of claim 11, wherein said internal compartment  
19 comprises a pharmaceutically acceptable osmotically-effective compound.

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21           13.    The membrane system of claim 12, wherein said internal compartment  
22 comprises a pharmaceutically acceptable hydrogel polymer.

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24           14.    The membrane system of claim 12 or claim 13, wherein said hydrophilic  
25 substance exhibits an aqueous solubility responsive to osmotic pressure and/or ionic strength  
26 of said osmotic core.

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28           15.    The membrane system of claim 12 or claim 13, wherein said hydrophilic  
29 substance exhibits an aqueous solubility responsive to said osmotically-effective compound.

1  
2 16. The membrane system of claim 12 or claim 13, wherein said interior wall  
3 comprises a polymer composition and said hydrophilic substance exhibits an aqueous  
4 solubility responsive to degree of hydration of said polymer composition.  
5

6 17. The membrane system of claim 11, wherein said internal compartment further  
7 comprises an expandable layer.  
8

9 18. The membrane system of claim 17, wherein said expandable layer comprises  
10 an osmotically-effective compound.  
11

12 19. The membrane system of claim 18, wherein said interior wall comprises a  
13 hydrophilic substance.  
14

15 20. The membrane system of claim 19, wherein said hydrophilic substance  
16 exhibits an aqueous solubility responsive to osmotic pressure and/or ionic strength of said  
17 osmotic core.  
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19 21. The membrane system of claim 19, wherein said hydrophilic substance  
20 exhibits an aqueous solubility responsive to said osmotically-effective compound.  
21

22 22. The membrane system of claim 19, wherein said interior wall comprises a  
23 polymer composition and said hydrophilic substance exhibits an aqueous solubility  
24 responsive to degree of hydration of said polymer composition.  
25

26 23. A controlled release dosage form comprising:  
27 an osmotic core;  
28 an interior wall surrounding at least a portion of said core osmotic core, wherein fluid  
29 permeability of the interior wall is responsive to osmolarity of said osmotic core; and

1 a fluid-permeable exterior wall surrounding the interior wall.

2  
3 24. A controlled release dosage form comprising:

4 an osmotic core,

5 an interior wall in contact with the osmotic core, wherein fluid permeability of the  
6 interior wall is responsive to osmolarity of said osmotic core; and

7 a fluid-permeable exterior wall in contact with the interior wall.

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9 25. The controlled release dosage form of claim 23 wherein said osmotic core  
10 comprises a therapeutic agent.

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12 26. The controlled release dosage form of claim 25 wherein the osmotic core, the  
13 internal wall and the external wall act in concert to provide a controlled delivery of said  
14 therapeutic agent over an extended or sustained-release period of time.

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16 27. The controlled release dosage form of claim 26, wherein said therapeutic agent  
17 is delivered over a period of about 30 minutes to about 30 hours.

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19 28. The controlled release dosage form of claim 27, wherein said therapeutic agent  
20 is delivered over a period of about 4 hours to about 24 hours.

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22 29. The controlled release dosage form of claim 23, wherein said interior wall  
23 comprises a hydrophobic substance and a hydrophilic substance, and said exterior wall is  
24 semipermeable.

25  
26 30. The controlled release dosage form of claim 29 wherein the hydrophilicity of  
27 the hydrophilic substance is osmosensitive.

1           31.     The controlled release dosage form of claim 29, wherein said hydrophilic  
2 substance exhibits an aqueous solubility responsive to osmotic pressure and/or ionic strength  
3 of said osmotic core.

4  
5           32.     The controlled release dosage form of claim 29, wherein hydrophilic substance  
6 provides increased permeability of the interior wall in response to a decrease in the osmotic  
7 pressure and/or the ionic strength of said osmotic core.

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9           33.     The controlled release dosage form of claim 29, wherein said interior wall  
10 comprises a polymer composition and said hydrophilic substance exhibits an aqueous  
11 solubility responsive to degree of hydration of said polymer composition.

12  
13           34.     The controlled release dosage form of claim 29, wherein said inner wall  
14 comprises a member selected from the group consisting of hydrogel polymers,  
15 osmopolymers, osmotically-effective compounds, suspending agents, compounds for forming  
16 passageway, pore formers polypeptides, proteins, polysaccharides, cellulose derivatives,  
17 surfactants, synthetic polymers and inorganic polymers.

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19           35.     The controlled release dosage form of claim 34, wherein said hydrophobic  
20 substance comprises ethyl acetate or cellulose acetate; said hydrophobic membrane comprises  
21 hydroxyalkylcellulose; and said semipermeable substance comprises cellulose acetate.

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23           36.     A process for delivering an osmotically active formulation from an osmotic  
24 pump over an extended period of time comprising:

- 25           (i) disposing said formulation in an osmotic pump;  
26           (ii) exposing said osmotic pump to a fluid environment to cause delivery of said  
27 formulation therefrom in response to osmotic imbibition of fluid into said pump; and  
28           (iii) increasing the fluid permeability of said pump in response to decreasing  
29 osmolarity of said formulation.

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2 37. The process of claim 36 wherein said formulation comprises a therapeutic  
3 agent.

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5 38. The process of claim 37 wherein said therapeutic agent is delivered in an  
6 extended-linear, non-declining release profile over a period of about 30 minutes to about 30  
7 hours.

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9 39. The process of claim 38 wherein said therapeutic agent is delivered in an  
10 extended-linear, non-declining release profile over a period of about 4 hours to about 24  
11 hours.

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13 40. The process of claim 38 or claim 39 wherein said extended-linear release  
14 profile is a zero order release profile.

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16 41. The process of claim 38 or claim 39 wherein said extended-linear release  
17 profile is an ascending release profile.

18  
19 42. A membrane comprising a semipermeable membrane having a control  
20 membrane disposed thereon, the water permeability of said control membrane being  
21 responsive to changes in the osmolality of fluid contacting said control membrane.

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23 43. The membrane of claim 42 wherein the water permeability of the control  
24 membrane is inversely proportional to changes in the osmolality of fluid contacting said  
25 control membrane.

26  
27 44. An osmotic pump comprising:

28 an osmotic core;

29 a semipermeable membrane enclosing at least a portion of said core; and

1 a control membrane disposed between at least a portion of said semipermeable  
2 membrane and said core, the water permeability of said control membrane being responsive  
3 to changes in the osmolarity of said core.

4  
5 45. The osmotic pump of claim 44 wherein the water permeability of the control  
6 membrane is inversely proportional to changes in the osmolarity of said core.

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